

JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

July 16, 2018

Submitted Electronically via Regulations.gov

Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991-ZA49)

Justice in Aging appreciates the opportunity to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries and populations that have traditionally lacked legal protection such as women, people of color, LGBT individuals, and people with limited English proficiency.

We agree that the status quo must change in order to relieve older adults and all Americans from the burdens of high drug costs and ensure continued access to the broad range of prescription drugs. Older adults particularly need affordable access to a robust range of prescription drugs. In the 2013-2014 time period, over 90 percent of seniors reported having taken at least one prescription drug in the past 30 days, and over 40 percent had taken 5 or more.¹ Four out of five adults age 65 and older have multiple chronic conditions,² a characteristic that is linked to higher out-of-pocket drug costs. For example, Americans with one chronic condition spend five times more at the pharmacy each year than individuals without chronic conditions. Those with five or more chronic conditions spend over 20 times more.³ Even among Medicare beneficiaries with Part D coverage, out-of-pocket spending can be significant for the majority of seniors who live on modest incomes. In 2015, the average Part D enrollee spent almost \$500 on out-of-pocket drug costs, including premiums, while those who reached catastrophic coverage, spent over \$3,000.⁴

The problems of high drug prices and out-of-pocket costs cannot be solved with a single action. While we agree that consumers' out-of-pocket costs can be lowered through some of the

¹ Centers for Disease Control, Prescription drug use in the past 30 days, by sex, race and Hispanic origin, and age: United States, selected years 1988–1994 through 2011–2014 (2016), at 25 & Table 79, *available at* www.cdc.gov/nchs/data/abus/abus16.pdf#079.

² HHS Agency for Healthcare Research & Quality, Multiple Chronic Conditions Chartbook (2010), at 4-5, *available at* www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.

³ *Id.* at 11.

⁴ Kaiser Family Foundation, 10 Essential Facts about Medicare and Prescription Drug Spending, *available at* www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/.

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proposals outlined in the Blueprint, these actions will not solve the lynchpin issue of escalating drug prices. The Blueprint’s proposals that would provide additional negotiation leverage to private payers are limited. Moreover, to the extent these proposals incorporate increased restrictions on the range of drugs available to beneficiaries, they could result in unfavorable outcomes for consumers, including those with the lowest incomes and greatest needs. In other words, while these proposals offer some modest steps in the right direction, much more needs to be done to turn the tide on drug pricing and cost. For example, we urge HHS to work with Congress to open the Medicare program's ability to negotiate drug prices as a necessary tool to address the underlying issues of rising drug prices.

Furthermore, the Blueprint’s proposals do not address fundamental problems with the design of the Medicare Part D program. Though the program is supposed to give beneficiaries market power by allowing them to choose plans that best meet their needs, the actual workings of the program severely limit that power. Beneficiaries face a lack of transparency and a lack of predictability that seriously compromises their ability to choose the best “value” plan for them despite their best efforts. Beneficiaries make choices based on the relative costs of drugs among plans. Yet those costs, both in absolute terms and in relative terms among plans, can change at any time—or even multiple times—throughout the plan year. Beneficiaries are locked into their plan choice for a year while their plan and drug companies can and do change drug prices throughout the year. As we explain below, comprehensive drug pricing and policy reform must address this unfairness and provide more price stability for beneficiaries.

As advocates for low-income older adults, our specific comments and recommendations below focus on ideas for reducing out-of-pocket costs to Medicare beneficiaries while maintaining access and critical consumer protections. We first address specific proposals as they were raised in the Blueprint followed by other recommendations and feedback.

A. Increasing Competition

- *Distribution Restrictions.*

Justice in Aging supports the changes to the FDA risk evaluation and mitigation strategy (REMS) requirements proposed in the bipartisan CREATES Act (S. 974).

B. Better Negotiation

- *Allowing plans to only cover at least one drug in each of the drug categories instead of two.*

We oppose lowering the minimum number of drugs Part D plans are required to cover from two to one per class. Over 65 percent of seniors reported taking three or more prescription drugs and over 40 percent reported taking five or more in the last 30 days.⁵ These seniors already face challenges finding Part D plans that cover all of their prescription drugs. Changing the formulary standard from two drugs per category to one would exacerbate this challenge. Furthermore, Part D beneficiaries would face greater risk of not being enrolled in a plan that

⁵ CDC, *supra* note 1.

meets their needs should they be prescribed a new medication in the middle of the year or need to change their regimen.

This proposed change would hit low-income and dual eligible individuals, many of whom have multiple chronic conditions coupled with complex drug regimens, especially hard.⁶ In a recent rulemaking, the Centers for Medicare & Medicaid Services (CMS) restricted the ability of Part D Low-Income Subsidy (LIS) beneficiaries to change plans. Beginning in 2019, instead of having a continuous Special Enrollment Period (SEP) that allows LIS beneficiaries to change plans as needed, LIS beneficiaries will only be able to switch plans once per quarter. This limited SEP means more LIS beneficiaries with complex prescription drug needs could be stuck in a plan that does not suit them. Restricting the number of drugs per class that plans are required to cover would make it likely that more LIS beneficiaries would find themselves in this situation and, because of the interaction of these two policies, be unable to access needed medications.

Additionally, we note that reducing access to necessary medications increases overall costs for the health care system. When conditions are not properly managed, beneficiaries often end up needing additional health care services that Medicare pays for, like inpatient hospital stays and doctors' visits.

We likewise oppose any proposals to eliminate or reduce the coverage standards for the six protected classes. The protected classes policy recognizes that people with serious and complex conditions like cancer, HIV and mental illnesses need access to the full range of medications available because such access is critical for the treatment to be effective. It also ensures that beneficiaries with chronic conditions transitioning to Part D can continue with the regimens that were working for them. Continuing uninterrupted access is necessary to ensure that individuals with complex conditions maintain adherence.

- *Change to Star Ratings.*

The Blueprint proposes changing how the record of the Independent Review Entity's reversals of a Part D plan's adverse redetermination decisions impact the plan's star rating. HHS is concerned that the current star rating calculation discourages plans from appropriately managing high-cost drugs. It is our experience that the issue is exactly the opposite: CMS audits have consistently found that plans inappropriately manage high cost drugs by violating CMS utilization management rules and by failing to address appeals of denials in accordance with CMS procedural requirements. For example, in 67 percent of its 2017 audits, CMS found that a plan sponsor failed to properly administer its CMS-approved formulary by applying unapproved utilization management practices; in 64 percent, CMS found that plan sponsors misclassified

⁶ See CMS Center for Strategic Planning, Chronic Conditions among Medicare Beneficiaries, at 28 (2011), available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2011Chartbook.pdf.

coverage determination or redetermination requests as grievances and/or customer service inquiries.⁷

Beneficiaries rely on star ratings to help guide them when making decisions about plans. Serious access issues found in audits need to be adequately incorporated into the star rating system so that beneficiaries can get a fair and realistic picture of plan strengths and weaknesses. Therefore, we oppose the Blueprint's proposal to change how IRE reversals are reflected in star ratings.

- *Indication-Based Payments.*

We are concerned that indication-based payments could have negative consequences on beneficiaries. If Medicare prescription drug plans are paying a different amount based on how a drug is used, would they also vary the drug's formulary placement (and corresponding cost-sharing) based on the underlying condition? We are concerned that this could lead to discrimination against beneficiaries with harder to treat conditions. In addition, these differences would be almost impossible to communicate to beneficiaries who are comparing which plans cover their needed prescriptions at what cost. Conveying this variability through plan formularies available to beneficiaries, much less in Plan Finder, would be a near insurmountable challenge.

- *Part B to D.*

We recognize that moving some high-cost drugs from Part B to Part D could benefit some beneficiaries by providing them with more transparency and lower out-of-pocket cost sharing. However, we are concerned that it could result in higher cost-sharing for Qualified Medicare Beneficiaries who have no cost-sharing under Part B but would have to pay the Part D LIS copay. Furthermore, the cost-sharing for non-LIS beneficiaries could be higher for the most expensive drugs if they are placed on the specialty tier with up to 33 percent coinsurance versus the 20 percent Part B coinsurance.

We also have concerns about how this proposal would play out in hospital settings. Currently many hospital pharmacies are not part of Part D plan networks. When beneficiaries are receiving Part D drugs in hospital settings but are not admitted (e.g., in out-patient or observation status), they are charged full price for their Part D drugs received from hospital pharmacies and can only get out-of-network coverage in situations where they can show an emergency. For Part B drugs, beneficiary co-insurance, though often substantial, is at least limited to 20 percent. If more drugs are moved from Part B to Part D, there will be a need to ensure that hospital pharmacies are part of plan networks or to otherwise address the current problem beneficiaries face with surprise high charges for drugs. Any change must ameliorate rather than exacerbate the current problems in hospital settings.

⁷ CMS, 2017 Part C and Part D Program Audit and Enforcement Report (May 2018), available at www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017ProgramAuditEnforcementReport.pdf.

For these reasons, we recommend HHS study this proposal further before taking steps to test or implement it.

- *Site neutrality between inpatient and outpatient setting.*

We support this proposal to adopt a site-neutral payment policy that mitigates the effect of hospital and facility fees on beneficiaries. This issue is especially problematic for Medicare beneficiaries who are in the emergency room or on observation status. High hospital fees can add to the burdens they already face because they are in Part B status, sometimes for extended periods.

- *Allowing mid-year formulary changes for single-source generic price increases.*

We have concerns about this proposal. Based on the fact that plans do not have contracts with single source generic manufacturers, it proposes to give plans the option to change benefit design including, we assume, moving the generic drug to a different tier mid-year if a generic manufacturer changes prices. This appears to us to be one more instance of where market risk is placed on the beneficiary rather than on the plan, which is in a much better position to assess and plan for that risk.

Beneficiaries pick plans annually based on pricing information available to them and they are then locked in until the next enrollment period. They are consumers buying insurance and insurance is, by definition, an instrument to limit risk.

As discussed in our comments under “Part D End-of-year statement on drug price changes and rebates collected,” beneficiaries already bear the risk of significant mid-year price changes for drugs appearing on co-insurance tiers. Plans have contracts with manufacturers for supply of those drugs but those contracts do not guarantee price stability for beneficiaries. Beneficiaries are locked in while plans and manufacturers are not. Adding generics to the types of drugs where risk is shifted to beneficiaries just makes the problem and the unfairness worse.

C. Create Incentives To Lower List Prices

- *Medicare Drug Pricing Dashboard.*

We support the proposal to highlight price increases and generic competition on Medicare’s drug pricing dashboard. This is the type of information transparency that can help stakeholders better understand drug pricing and inform policy responses.

- *Fiduciary duty for Pharmacy Benefit Managers.*

We recommend further examination of PBMs’ involvement in drug pricing and how to ensure that they are incentivized to operate in a manner that will lower drug prices and out-of-pocket costs. Obligating PBMs to act as a fiduciary for the payers helps only to the extent to which the payers have the proper incentives to ensure beneficiaries have affordable access to the full range of drugs they may need.

- *Reducing the impact of rebates.*

We appreciate that HHS is seeking to develop a more transparent approach to the treatment of rebates. As HHS has noted, the current system is not resulting in lower costs for beneficiaries at

the point of sale, and may shift government costs to the catastrophic phase of the benefit. In seeking to make improvements, we urge HHS to make careful evidence-based determinations to ensure that the incentives promote the greatest possible increase in beneficiary access to affordable drugs. We also urge HHS to develop a system that allows beneficiaries to make fully informed choices among their drug coverage options.

- *Copay discount cards.*

While we recognize that discount cards can reduce out-of-pocket costs for certain beneficiaries for a limited period of time, we are concerned about unintended consequences of allowing discount cards in the Medicare program. First, coupons do not address the underlying problem of growth in drug prices. Second, it is also possible that coupons raise prices for others in the system. Third, coupons can be burdensome on consumers, and it can be particularly difficult for those with limited income and resources to find and print these coupons. It is also unclear that the consumer using the coupon is getting the best price for the drug, given geographic and pharmacy variation in out of pocket costs. Additionally, we are concerned that coupons are often time limited and used to increase brand loyalty, making it more difficult for consumers to switch to a less expensive drug.

- *Removing catastrophic coverage co-pay, effectively giving Part D an out-of-pocket spending limit.*

We generally support putting an upper limit on Part D out-of-pocket spending to reduce financial burden on Medicare beneficiaries who have high-cost prescription drug needs. However, the proposal does not clarify which entity would be responsible for the costs once a beneficiary meets their out-of-pocket cap. Making Part D plans liable for more costs in the catastrophic phase would likely lead to some cost-shifting back to beneficiaries through higher Part D premiums. Spreading the burden across all Part D enrollees this way may be acceptable.

We caution, however, that the proposal to couple an out-of-pocket cap with excluding manufacturer discounts from TrOOP calculations would extend the amount of time it takes beneficiaries to reach the catastrophic phase. Thus, if both these policies were implemented, the financial burden would remain on those with already high costs.

D. Reduce Patient Out-of-Pocket Spending

- *Eliminating cost-sharing on generic drugs for low-income beneficiaries.*

We support eliminating cost-sharing on generics for LIS beneficiaries. Even a minimal amount of cost-sharing can be a barrier to access. However, we ask clarification of whether this policy will apply to “non-preferred” or single-source generics with high prices. We urge HHS to apply the zero co-pay policy to all generics, both to take the cost burdens off low-income beneficiaries and to encourage adherence. If the \$0 cost-sharing will not apply to all generics, effectively communicating the limits of the policy along with its value will be challenging. It will be important for HHS to ensure that this change in policy not add confusion for LIS beneficiaries who may logically expect that any “generic” will have \$0 cost-sharing.

- *Part D end-of-year statement on drug price changes and rebates collected.*

Beneficiaries need information in real time and need to be able to act on that information. We believe that pharmacists should be both enabled and encouraged to tell beneficiaries at the point of sale about changes in prices. Year-end statements, though including important data, are of little value to beneficiaries, particularly because, taken alone, they do not help beneficiaries decide which plan they should join in the next year.

This question raises a more basic concern about beneficiary access to needed information that the Blueprint does not address. A fundamental assumption of the Part D program is that beneficiaries shopping among plans will be able to choose a plan that best meet their needs and that their market-based choices will maximize value and act as a brake on costs.

The current design of Part D, however, includes major market distortions. Beneficiaries are supposed to make rational decisions by reviewing comparative costs based on their prescription drug usage. Once they make those choices, they are locked into a plan for a year unless they have a Special Enrollment Period. However, though beneficiaries are locked in, plans are not. Plans' contracts with drug suppliers can—and do—change drug prices as frequently as every two weeks. Those changes are not in lockstep. Prices for a drug can go up substantially for one plan and not for another. An individual who made a careful and rational choice in November during the Annual Enrollment Period can find on January 1 (or in February, May or any other time) that the chosen plan is no longer the most economical for the same drugs. Despite these changes over which they have no control, beneficiaries have no way to respond because they are locked in. It is one thing (though certainly problematic) for a drug's price to go up across the board mid-year, but it is quite another for the drug's relative prices to change significantly between plans with no notice and no recourse for beneficiaries. Moreover, since CMS is prohibited by statute from regulating or even inquiring into pricing relationships between plans and drug manufacturers, there is no regulator looking at how or why these variations occur and providing oversight of this system.

This is the antithesis of an open and transparent market. HHS needs to address the unfairness and opacity of the current system and develop solutions that provide more price stability for beneficiaries and ensure that the market choices they make are meaningful.

- *Federal preemption of contracted pharmacy gag clause laws.*

We agree with the position CMS took in its May 17, 2018, memo on “Unacceptable Pharmacy Gag Clauses.” This policy clarification should help increase transparency and ensure beneficiaries are paying the lowest out-of-pocket amount available to them. However, we recognize that this change will benefit relatively few beneficiaries and does not address the underlying issues of high drug prices.

E. Additional Feedback

- *Simplify Part D Plan Tiering & Shopping.*

Part D Plans can be extremely complicated with multiple tiers for “preferred” and “non-preferred” drugs as well as tiers for preferred and non-preferred pharmacies, including preferred and non-preferred mail order pharmacies. These multiple layers of pricing makes

shopping for a plan and comparing between plans extremely difficult. Making matters more confusing, “preferred” drugs or pharmacies, although overall less expensive than “non-preferred,” are not necessarily associated with lower out-of-pocket costs for each particular drug a beneficiary needs.

Moreover, the higher cost-sharing tiers usually use co-insurance, making it nearly impossible for beneficiaries to estimate their own out-of-pocket costs. In 2018, more than 4 out of 10 Part D beneficiaries were enrolled in plans with 33 percent coinsurance for specialty tier drugs.⁸ As noted in our comments on reducing out-of-pocket spending, beneficiary liability for co-insurance tiers can change, sometimes dramatically, when the price of a drug to the plan changes.

Therefore, we recommend that HHS look at ways to simplify formulary tiering and improve plan shopping tools to reduce the burden on beneficiaries who are navigating a large amount of information to try to make the plan choice that is best for them. We also urge HHS to consider ways to make it easier for individuals applying for a formulary exception to also apply for a tiering exception if applicable. It may be possible, for example, to have a box on formulary exception request forms to ask also for a tiering exception if available.

- *Eliminate the Asset Test for the Low Income Subsidy.*

We strongly encourage HHS to consider and support policies that will more directly address out-of-pocket costs for beneficiaries. For example, eligibility for many discount cards previously available to lower income beneficiaries did not include an asset test. HHS should support increasing or removing the asset limit for the LIS. The asset test unfairly penalizes low-income beneficiaries for putting aside modest savings for retirement and emergency expenses, forcing them to spend down their assets. Asset tests also discourage beneficiaries from attempting to enroll. Even those who would qualify find that collecting information on assets is a challenge and many give up simply because of the paperwork burden, which can be especially challenging for beneficiaries who are ill or have disabling conditions. As a result, many Part D enrollees with minimal income remain ineligible for this crucial cost-sharing assistance. This change would also simplify the LIS application processing burdens for the Social Security Administration, and thus reduce administrative costs.

- *Medicaid Formulary Changes.*

We oppose allowing state Medicaid programs to create closed prescription drug formularies. We are concerned that states would use this authority to severely limit their drug coverage in order to cut costs, leaving Medicaid beneficiaries without access to necessary medications. Unlike individuals with private insurance or Medicare, Medicaid beneficiaries cannot switch to another insurer if their drugs are not covered and, because they are by definition low-income, they cannot afford to pay for prescription drugs out-of-pocket. Narrowing formulary options for

⁸ Kaiser Family Foundation, Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing (May 17, 2018), available at www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.

the poorest individuals with the most complex needs is not the right approach to attack high drug prices.

Conclusion

In conclusion, we urge HHS to consider not only the impact of individual proposals on beneficiaries, but also the combined impact of proposals if they are implemented together. Interactions between policy and systems changes could either exacerbate negative impacts or negate improvements in out-of-pocket costs, if one change offsets another. We also encourage HHS to involve Medicare beneficiaries, including low-income older adults and dual eligibles, in the development and implementation of any proposals it chooses to move forward. It is critical to consider how these changes would and do affect beneficiary access based on real experiences, not only theory and projections.

Thank you again for the opportunity to submit comments on these proposals. If any questions arise concerning this submission, please contact me at jgoldberg@justiceinaging.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer Goldberg". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jennifer Goldberg
Directing Attorney